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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/508,147

Applicant(s)
SUN, YI

Examiner
Cynthia B Wilder

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 29, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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FINAL ACTION

1. This application has been transferred from Examiner Hope Robinson in Art Unit 1653 to Examiner Cynthia Wilder in Art Unit 1637. All further correspondence should be directed to Examiner Cynthia Wilder whose contact information appear at the end of this office action.

2. Applicant's amendment filed in paper No. 14 is acknowledged. Claims 2-4 have been amended. Claims 2-4 are currently pending. Claim 1 has been withdrawn from consideration as being drawn to a non-elected invention.

3. All of the amendments and arguments have been fully reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Objections and Rejections

5. The objection of to the specification is withdrawn in view of Applicant's submission of drawing in Paper No. 12. The objection to the abstract is withdrawn in view of Applicant's submission of an abstract. The objection to the Oath/Declaration is withdrawn in view of Applicant's submission of a supplemental Oath/Declaration with the corrected priority information. Accordingly, priority has been granted for the priority document 60/065,740 filed November 17, 1997. The objections to the claims have been withdrawn in view of Applicant's amendment to the

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claims. The claim rejection under 35 U.S.C. 112 first paragraph directed to claim 4 is maintained for the reasons discussed below. The claim rejections under 35 U.S.C. 102 (b) directed to claims 2 and 3 as being anticipated by Bian et al. are withdrawn in view of Applicant's establishment of priority. The claim rejection under 35 U.S.C. 102(b) directed to claim 3 as being anticipated by Draper et al. is maintained for the reasons discussed below.

Claim Rejections - 35 USC § 112

6. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. Claim 4 is directed to an isolated DNA fragment comprising the sequence set forth in SEQ ID NO: 23. The sequence comprises a repeat of one of the known motifs of the p53 binding sites. However, there is no indication in the description of the significance of this particular sequence, thus the provision of a DNA fragment comprising two such motifs linked together does not provide adequate written description. The paper copy of the sequence listing provides the sequence, however, the specification does not contain a single reference to this sequence or any of the required information about the sequence such as biological activity or a description of any characteristics/attributes of the claimed sequence. Thus, given the claim breath and lack of guidance as discussed above the specification fails to provide an adequate written description of the claimed invention. Accordingly,

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one of skill in the art would not be able to practice the claimed invention at the time of filing commensurate in scope with the claim.

7. Applicant traverses the rejections on the following grounds: Applicant states the application clearly states that concatamers of certain DNA sequences are useful and describe how to make such concatamers. Applicant contends that the sequence motif which is concatenated in claim 4 is clearly shown throughout the specification and noted to be an important motif for the p53 binding site. Applicant state that while not specifically described in detailed, this motif, as well as how to make and use the concatenated p53 binding site motifs is described throughout the specification. Applicant respectfully request the rejection be withdrawn for claim 4.

8. The arguments have been thoroughly reviewed and considered but are not found persuasive. First of all, Applicant fails to specifically point to a passage or passages in the specification that teaches the sequence motif which is concatenated in claim 4. As noted in the prior office action of Paper No. 10, there is no indication anywhere in the specification the significance of the claimed sequence recited in claim 4. There is not a single reference to this sequence in the specification and no required information about the sequence is given anywhere in the specification. To reiterate, there is no description of the claimed sequence in the specification. Therefore, one of skill in the art would not know how to make or use the claimed invention commensurate in scope with the claimed invention. Accordingly, the rejection is maintained.

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Claim Rejections - 35 USC § 102

9. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Draper et al. (U.S. patent No. 5,248,670, September 28, 1993). The claim is directed to an isolated DNA fragment comprising the sequence contained in SEQ ID NO: 10. Draper teaches the sequence set forth in SEQ ID NO: 10 with a 100% sequence identity (see alignment). Thus, the limitation of the claim is met by the reference.

10. Applicant traverses the rejection on the following ground: Applicant request that the Examiner point out more clearly the passage in Draper that sets forth this sequence. Applicant argues that nowhere in Draper is there taught or suggested a sequence that binds to the consensus p53 DNA binding site. Applicant request the rejection be withdrawn.

11. The arguments have been fully considered but are not found persuasive for the following reasons: With respect to Applicant request to point out more clearly the passage in Draper that sets forth the claimed sequence, Applicant is directed to the sequence alignment and sequence SEQ ID NO: 4 of Figure 4 in the Draper patent. In response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the feature upon which Applicant relies (i.e., a sequence that binds to the consensus p53 DNA binding site) is not recited in the rejected claim 3. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In view of the foregoing, the rejection directed to claim 3 under 102(b) is maintained.

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New Ground(s) of Rejections

Claim Rejections - 35 USC § 102(a)

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

13. Claims 2-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Bian et al. (Carcinogenesis, Vol. 17, No. 12, pages 2559-2562, 1996). The claims are drawn to isolated DNA fragments comprising the sequence contained in SEQ ID NOs: 8 or 10. Bian teaches the sequences set forth in SEQ ID NOS: 8 and 10 with a 100% identity (see pages 2560, right column, lines 32-33 of the reference). Thus, the limitation of the claims are met by this reference.

Conclusion

14. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

October 8, 2002


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

10/9/02